ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

ASN 50 years

Kidney News

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Telemedicine Poised to Help Some Patients with CKD

For patients with chronic kidney disease (CKD), getting to regularly scheduled doctors' appointments can pose a challenge. Whether a patient lives too far from a clinic, has limited mobility owing to various comorbidities, or does not realize the severity of their illness, some may not make the trip. However, a new study presented at ASN Kidney Week 2015 shows that patients may not always have to travel far to receive care.

"Few studies, if any, have evaluated renal clinic visit compliance among patients with CKD," said Rajeev Rohatgi, of the Mt. Sinai School of Medicine in New York, NY, and the study's main author. However, evidence points to the fact that patients who live far from a nephrology practice are hospitalized more frequently and with higher mortality than those who live closer, he said. Thus, he became interested in evaluating whether care delivered remotely via videoconferencing technology, also known as telemedicine or telenephrology, could be as beneficial to patients as in-person conventional care for managing the disease.

Rohatgi and his team conducted a retrospective observational study and analyzed clinical outcomes of 238 patients with CKD who were enrolled at the Bronx Veterans Affairs Medical Center. Among these patients, 121 lived near the medical center (an average of 10.2 ± 1.3 miles), and 117 lived much further away (an average of 63.5 ± 2.2 miles). The 117 patients who lived further away were then enrolled in telenephrology sessions at the much closer Castle Point campus of the Hudson Valley VAMC for their CKD care, and were evaluated remotely by a Bronx VAMC nephrologist from 2008 to 2014 (1).

Both the Hudson Valley and Bronx VAMC institutions had telemedicine resources available, such as videoconferencing equipment, HIPAA-compliant internet lines, and technical support.

The team found that the kidney disease characteristics—initial creatinine, eGFR, distribution of CKD stage, and urine protein—of the two groups were similar. However, the frequency of attending appointments was greater in the telenephrology group (70.8%) versus the conventional care group (61.8%), which was driven by a greater frequency of cancelled visits in the conventional care group (27.9%) versus the telenephrology group (15.8%).

Moreover, prior to enrolling in tel-

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Changes to Gut Microbiota May Contribute to Inflammation and Vascular Complications in Diabetic Kidney Patients

By Sara Leeds

Scientists have long known that microorganisms living within the gut aid in many important bodily processes such as digestion, production of various vitamins, and immune function. They are also learning more about how personal microbiomes influence other aspects of health. A new study, presented at ASN Kidney Week 2015, found that a shift in the gut's microbiota in combination with higher plasma levels of a marker of bacterial toxins may be linked with chronic inflammation and endothelial dysfunction among patients with type 2 diabetes and advanced chronic kidney disease (CKD).

Ruchi Singh, PhD, of the Texas Tech Health Science Center, was the lead author of the study. She and her team assessed gut microbiota and measured markers for compromised metabolism, leaky gut syndrome, and diminished clearance that affected patients with diabetic nephropathy. These patients were matched against healthy controls.

The markers measured included inflammatory cytokines (transcription ne-

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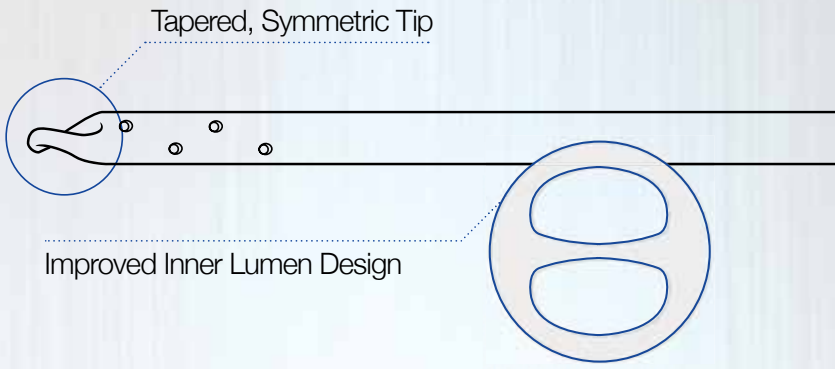

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Telemedicine

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enephrology sessions, more than 50% of patients who lived far from a VA nephrologist either cancelled or missed their scheduled appointments at the Bronx VAMC. However, after enrolling in telenephrology, this was reduced by nearly half. The researchers speculate that missing a large number of appointments leads to worse renal outcomes, but delivering care to patients with CKD locally improves the likelihood that they will attend their scheduled visits, potentially resulting in clinical outcomes equal to those for conventional care.

"These data imply that remote delivery of care via telenephrology has the potential to deliver equitable, patient-centered care to a geographically diverse patient population while alleviating disparity in care," Rohatgi said. "Although not appropriate in all instances, remote monitoring can help deliver excellent care in areas of nephrology such as peritoneal dialysis, hemodialysis, kidney transplantation, and in-patient renal consultation."

The concept of telemedicine is nothing new, but it is becoming more feasible and common as technology improves at an ever faster pace. On January 1, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a new provider reimbursement code for "non-face-to-face care coordination services" for Medicare beneficiaries with multiple chronic conditions (2). In all, 27 states along with the District of Columbia have laws enforcing coverage for telemedicine (3).

Still, current rules in the US limit telehealth services, which can only be administered in rural counties and in more urban health facilities known as "originating sites" near areas with a shortage of health care providers. Patients cannot receive telehealth services from their homes. In addition, only certain practitioners are authorized to administer a limited number of services, and remote patient monitoring is not covered by Medicare (4).

To combat these limitations, four members of the US House of Representatives [Mike Thompson (D-CA), Gregg Harper (R-MS), Diane Black (R-TN), and Peter Welch (D-VT)] introduced the Medicare Telehealth Parity Act of 2015 in the summer of 2015, which would consider a patient's residence an originating site for home dialysis services, and also allow them to take part in monthly telehealth appointments (4). ASN is strongly supportive of this legislation and is actively advocating for its passage. In addition, Senators Roger Wicker (R-MS) and Brian Schatz (D-HI) are spearheading a bipartisan working group introducing similar legislation in the Senate aimed at improving telehealth services.

Among other barriers to telemedicine, doctors may have to work with someone in another state, where they aren't licensed. However, the Interstate Medical Licensure Compact of the Federation of State Medical Boards was recently introduced to help make it easier for physicians to become licensed in multiple states. As of July 2015, 10 states have enacted the compact (5).

Despite the roadblocks, Rohatgi is optimistic about the future. "Although face-to-face services will likely always be needed, we hope our preliminary data can act as a first step in developing a clinical trial to confirm remote monitoring is safe and effective for kidney patients, he said. "If this can be confirmed, we believe that the private sector should strongly consider implementing this model of patient-centered care."

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Gut Microbiota

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crosis factor α [TNF-α], interleukin–6 [IL-6]) in conjunction with fibroblast growth factor 23 (FGF-23), the vasoconstrictor endothelin 1 (ET-1), and levels of lipopolysaccharide (LPS).

"We were also interested in plasma zonulin," Singh said, referring to a protein often released by bacterial toxins. It can assist in opening tight junctions within the small intestine, and can be indicative of leaky gut syndrome. "Hence, we selected it as a biomarker."

As part of the study, participants filled out a survey that helped researchers analyze and compare their dietary habits. Microbiota shifts are mainly caused by metabolic disorder, Singh said, adding that good dietary habits, regular exercise, and maintaining a healthy lifestyle may help individuals avoid shifts in microbiota.

"We observed significant gut microbiome shifts in CKD patients with diabetes compared with age-, gender-, and diet-matched control subjects," Singh said. Patients with type 2 diabetes and advanced CKD exhibited a greater proportion of LPS-producing bacteria. Furthermore, significantly elevated levels of circulating serum zonulin pointed to a prominent increase in gut permeability.

"This is an intriguing novel therapeutic target, and it will be interesting to see if gut-directed therapies can be developed that will dramatically halt or delay disease progression," said Wei Ling Lau, MD, of the Division of Nephrology and Hypertension at the University of California, Irvine, who was not involved with the study. However, Lau warned that the altered gut microbiome and "leaky gut syndrome" are not necessarily specific to diabetic patients with CKD. "It may also be interesting to investigate different etiologic subgroups of CKD (e.g., diabetic, hypertensive, glomerular) to compare microbiome composition and inflammatory markers."

Dominic Raj, MD, Director of the Division of Renal Disease and Hypertension at GW Medical Faculty Associates in Washington, DC, said he thought it a good idea to examine the link between microbiome shifts, zonulin, and inflammation in patients with diabetic nephropathy.

Raj was also not involved with the study, but said he would be curious to learn more about the specific microbial groups that are abundant or decreased in these patients as well as whether or not the microbiome shift precedes the onset of CKD. Especially interesting is that in disease states such as CKD, bacterial abundance is generally increased, but diversity is generally decreased. This is contrary to what was observed.

"Overall, this is an excellent pilot study, that shows us we still have a lot of unknowns," he said. "It is an excellent step in the right direction."

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Letter to the Editor

Prior to publication of the article "ASN's Options for Helping Nephrologists Maintain Career Excellence" in the December Kidney News*, authors ASN Councilor Mark E. Rosenberg, MD, FASN, and Executive Director Tod Ibrahim invited ABIM President and CEO Richard J. Baron, MD, MACP, to review the draft article and to respond in a subsequent issue.*

Here, Kidney News *publishes the response.*

December 15, 2015

To the Editor, *Kidney News*:

Nephrologists are justifiably proud of their knowledge and skills, and most of them invest considerable effort in staying current in their practice of today's medicine—keeping up with the rapid changes in the field since they completed their training. Having a substantive, meaningful, peer-issued credential, such as that provided by the American Board of Internal Medicine (ABIM), proudly recognizes and celebrates nephrologists' efforts to stay up-to-date and powerfully supports the goal of preserving physician agency and autonomy at a time when both are threatened.

That is why we were disappointed to read the opinion column in December's *Kidney News* by Rosenberg and Ibrahim (1) on behalf of the American Society of Nephrology (ASN) Council. We do not think it reflects a current view of many changes undertaken by ABIM as a result of substantive ongoing conversations with multiple internal medicine subspecialty societies, including ASN.

Reporting of MOC status

ABIM has always committed to ensuring that diplomates with lifetime certifications remain certified. This commitment was conveyed and reaffirmed to ASN and other societies repeatedly in 2013 before rolling out new MOC requirements. In order to make certification a more continuous credential and provide diplomates with an independent, third-party process to demonstrate to themselves and their colleagues that they are staying current with knowledge and practice, ABIM added a new reporting element in 2014—"meeting MOC requirements"—that applied to all ABIM Board Certified diplomates.

After the launch of the program in 2014, ABIM heard loudly and clearly that the "meeting requirements" language felt overly punitive and failed to emphasize the voluntary recognition the credential was meant to speak to. In response to this feedback from diplomates and medical societies (including ASN), ABIM leadership chose to change the language to "participating in MOC." (2)

MOC activities approved for nephrologists

ABIM continues to award MOC points for the valuable CME and Practice Assessment products offered by ASN, including NephSAP and KSAP (3), and for the ASN Kidney Transplantation PIM and ASN Dialysis PIM (4, 5). This summer, ABIM also announced an effort to recognize more of what physicians are doing in practice by awarding MOC points for many CME activities, thanks to a new partnership (6) forged with ACCME. Accredited CME providers will now be able to use one unified, shared system to record information about both CME and ABIM MOC activities, giving nephrologists many more options to earn CME that also qualifies for MOC credit.

As of December 4, 2015, nearly 2500 ASN-sponsored CME activities earned ABIM diplomates MOC credit—with more than 1800 of those activities completed by physicians with a primary certificate in Nephrology. That number will grow as we approach the end of the year and diplomates complete their year-end requirements.

We encourage ASN and practicing nephrologists to be engaged in efforts to improve ABIM's programs. As part of this process, ABIM recently solicited formal feedback from societies regarding the Assessment 2020 report (7), an independent report focused on the future of assessment. To date, ABIM has received formal feedback from more than a dozen societies and hopes to receive feedback from ASN.

Initial certification requirements

With regard to the issue of procedural documentation, members of the ABIM Nephrology Specialty Board had several conversations with leaders of the ASN Training Program Director (TPD) Executive Committee to prepare a list of procedures including placement of hemodialysis catheters, performance of kidney biopsies, and the spectrum of dialysis modalities for which ABIM and ACGME require competence be attained during training. Throughout ABIM's history, training requirements have always been the purview of ABIM, but the Board has always worked with society colleagues to determine precisely what they should be. The Nephrology Board worked closely with ASN TPD leadership to better understand the procedural and dialysis-related experiences of nephrology trainees.

After this jointly prepared list was assembled, it was presented to the entire ASN TPD Executive Committee, which decided that this was a very important matter but recommended against a requirement for such documentation and recommended that these issues be discussed in detail at a subsequent TPD meeting. The ABIM Nephrology Board has not pursued this further.

Governance and finances

Other issues raised in the ASN editorial include ABIM governance and finances. ABIM believes that they have been transparent about the changes in the ABIM governance structure and the process to establish the specialty boards, as well as the roles and composition of the boards. A complete description of ABIM's governance structure is available on ABIM's website (8) and details the roles and responsibilities of the Board, Council, Specialty Boards, and Exam Writing Committees. The names of the members of the ABIM Nephrology Board (9)—comprised mostly of active ASN members—are listed publically on the ABIM website.

ABIM leaders believe that the new ABIM governance structure affords far greater opportunity for ASN and other specialty societies to shape ABIM processes and decision-making, with six ASN members in ABIM leadership positions on the Specialty Board and ABIM Council. This is far more than was the case with the prior governance structure. We believe that the new governance structure will be advantageous to nephrologists and ASN, and there have already been numerous meetings and discussions between ABIM and ASN leadership that we fully expect will continue. Various meetings have included members of ASN Council, leaders of the ASN educational community, ASN Training Program Directors (TPD) Executive Committee members, and others.

Finally, over the last two years, ABIM increased its fiscal transparency (10)—providing IRS 990 forms and audited financial reports on its website. While not a common practice for most boards and medical societies, it was felt that this was an appropriate indicator of the importance placed on transparency and effective stewardship of diplomate fees by ABIM. ABIM has invited financial scrutiny and was pleased that ASN leadership, their CFO, and ASN's independent auditor recently spoke with ABIM's CFO to discuss finance-related questions ASN had about ABIM.

Credentials that speak to the value and contribution of individual physicians are even more important in a world where physicians risk being seen as cogs in a machine, adding no value of their own to the overall system. Both the challenges and the value of this were accurately foreseen by some of the great nephrologist leaders of ASN and ABIM over the years and articulated very clearly by Relman, who opined: "If there is legitimate concern about the relevance of the tests used for recertification, then it should be up to the specialty boards to see that the examinations are suitable. If there is reason to believe that the testing procedures are arbitrary, unnecessarily stressful, or unfairly administered, then ways must be found to remedy these defects. . . . [B]ut for a profession that takes such pride in its self-imposed discipline, total abandonment of the recertification idea would be a mistake." (11)

We want to continue to work together to redesign the MOC program so that it is a source of pride for all internists and subspecialists and something that embodies responsible self-regulation at a challenging time for all physicians. It is our sincere hope that ASN will work constructively with ABIM and other internal medicine subspecialty societies to achieve this goal. ABIM is eager to continue to work in close collaboration with ASN.

The Editorial concluded with four options ASN leadership is considering going forward, all four of which would remove nephrologists from the larger community of internal medicine and the broadly respected framework for which

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Letter to the Editor

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being "board certified" has stood. We hope ASN leadership will find a way to work with other internal medicine societies and ABIM to strengthen our community and keep nephrology firmly within internal medicine.

Sincerely,

Richard J. Baron, MD, MACP
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Major Win for Research in US Congress 2016 Budget Deal

By Grant Olan

On December 18, 2015, Congress passed a budget deal that averted a government shutdown and makes substantial new investments in federal research, a top ASN policy priority. The deal increased the budgets for the National Institutes of Health (NIH), including the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the Department of Veterans Affairs (VA) Research Program.

ASN has been working in partnership with the research advocacy community to build support in Congress for these increases since Congress enacted deficit reduction measures in 2010 that cut research budgets.

The deal increases the budget for NIDDK in 2016 by $68 million, a $30 million increase over President Barack Obama's budget request. NIDDK's total budget for 2016 is $1.9 billion. The total represents 6.31% of total NIH funding, an increase from 5.77% in 2015 (Table 1).

NIH received an overall increase of $2 billion, a $1 billion increase over President Obama's budget request. NIH's total budget for 2016 is $32 billion. The deal also increases the VA Research Program's budget by $41.8 million, bringing the VA Research Program's total budget to $630.7 million in 2016.

"ASN commends Congress, especially the chairs of the House and Senate Appropriations Committees, Senator Roy Blunt (R-MO) and Representative Tom Cole (R-OK), for their commitment and support of the US research enterprise," ASN Research Advocacy Committee Chair Frank "Chip" Brosius, MD, remarked. "After years of fiscal belt tightening, these crucial new investments will help NIH and NIDDK shore up their depleted budgets so that they can make investments in the next generation of scientists whose research discoveries and innovations may be the key to finding a cure for patients with kidney disease."ASN has been working with a number of advocacy coalitions, including the Coalition for Health Funding, Ad Hoc Group for Medical Research, Friends of NIDDK, and Friends of VA Medical Care and Health Research, which successfully persuaded Congress to raise the overall budget caps for federal discretionary programs like NIH and the VA in both 2016 and 2017.

Table 1
NIH and NIDDK funding for Fiscal Years 2000–2015

Fiscal Year	NIDDK Actual Funding (in thousands)	NIH Actual Funding (in thousands)	NIDDK Funding as a % of NIH Funding	% Increase in NIDDK Funding	% Increase in NIH Funding
2010	$1,958,100	$31,238,000	6.27%	2.45%	2.27%
2011	$1,942,224	$30,916,345	6.28%	-0.81%	-1.03%
2012	$1,947,044	$30,860,913	6.31%	0.25%	-0.18%
2013	$1,835,015	$29,151,462	6.29%	-5.75%	-5.5%
2014	$1,745,177	$30,070,062	5.80%	-4.89%	3.15%
2015	$1,749,140	$30,311,349	5.77%	0.22%	0.80%
2016	$1,968,357	$32,084,000	6.31%	3.61%	6.64%

Gingrich: Why doubling NIH budget would benefit all of us

By Newt Gingrich, Bill Brazell

The following commentary originally appeared in Fox News Opinion on foxnews.com, the website of the Fox News Channel on December 21, 2015.

Imagine spending four hours a day, three days a week tethered to a dialysis machine just to survive. For many of the more than 20 million Americans—one out of every 10 adults—who suffer from chronic kidney disease (CKD), that life isn't theoretical. It's their daily reality.

But all taxpayers, not just those with kidney problems, have a reason to support a drastic increase in government funding for research: We, the taxpayers, are spending tens of billions each year to treat patients with kidney disease—the nation's ninth-leading cause of death—and yet we are investing very little in trying to cure it.

Every year, the federal government spends $80 billion through Medicare alone to treat CKD (and the real cost to taxpayers is much higher when we count spending through dozens of other programs), but the National Institutes of Health are able to devote less than 0.8% of that amount to research to prevent or cure it.

To make matters worse, the costs of treating CKD are increasing rapidly. Between 2008 and 2012, Medicare spending on CKD patients increased at a rate almost five times as fast as the rest of the program and now makes up one-fifth of all Medicare Parts A and B expenditures. Costs increase as patients progress through the disease, with a dialysis patient requiring nearly $90,000 per year. This makes end stage renal disease one of the most expensive chronic diseases.

Put another way, every patient kept off of dialysis saves taxpayers $250,000.

If we fail to solve this problem, then by 2030, one out of every six American adults will have CKD.

Take for example the particular form of CKD that one of us (Bill) inherited from his father. The NIH spends $41 million on polycystic kidney disease (PKD) research per year. Having sent 5,000 patients to the transplant list, PKD costs taxpayers 50 times more than that— $2 billion—annually via Medicaid and Medicare alone.

Of course, this total does not include the lost productivity of workers forced to retire early. Only 20 percent of the people on dialysis of working age have jobs. Nor does it account for the toll of the disease on caretakers, nor the devastation that too many early deaths wreak on families.

Bill's cousin Michael, a successful sales executive suffering from PKD, was torn from his family at the age of 35, leaving two young children to grow up without a father.

A treatment to slow the progression of PKD may now be close at hand. Thanks to research funded in part by the NIH and in part by the PKD Foundation, Bill is taking an experimental drug already approved for use in the European Union, the U.K., Japan and Canada. With just a little more spent on PKD research, even better treatments could soon follow, saving billions for years to come.

PKD is just one of more than 200 costly kidney diseases. For each, research is severely underfunded. An additional $1.5 billion over ten years could significantly reduce the $80 billion taxpayers are paying each year through Medicare to manage them. Simply delaying the onset of such illnesses by a few years would save American taxpayers billions of dollars annually—forever.

It is hard to imagine a smarter, and more compassionate, fiscal policy.

Kidney disease, of course, represents just one of many debilitating conditions for which the NIH funds crucial basic research. Heart disease, cancer, stroke, arthritis, Alzheimer's—swifter progress toward cures would benefit all of those who suffer from these terrible diseases, to say nothing of taxpayers at large.

We have proposed doubling the NIH budget to $60 billion and reforming it to reduce bureaucracy, focus resources on basic research for the most expensive and prevalent health problems, and give the director more flexibility to redirect funds where they are urgently needed.

Leaders in both the House and Senate have taken important steps in this direction. The new budget deal passed by the House would boost NIH's budget by $2 billion, the largest increase the NIH has received in 12 years. That's a great first step.

Moreover, the 21st Century Cures Act, which recently passed the House 344–77, is a bipartisan effort to promote medical discoveries using the newest technology.

Now before the Senate, this bill, among other provisions, mandates $10 billion in new NIH funding over the next five years. Furthermore, Reps. Diana DeGette, D-Colo., and Dr. Michael C. Burgess, R-Texas, have called for the Congressional Budget Office to factor in the savings from preventive health measures when assessing the financial impact of proposed legislation.

In the Senate, Lamar Alexander of Tennessee, Ron Johnson of Wisconsin, and Jerry Moran of Kansas, all Republicans, have championed increased funding for basic research. Others, including Charles Schumer, Democrat from New York, have advocated increased funding for medical research in general and kidney disease in particular.

Medical research is a bipartisan value, but Congress needs to know that its constituents care. One of the best things you can do for your health and for that of your loved ones is to call on your congressional representatives to double the NIH budget on an ongoing basis.

In the short run, ask your senators to approve the 21st Century Cures Act's increased funding for NIH so that researchers will know they can count on the money and continue to take the kinds of big risks that lead to big cures.

Newt Gingrich, a Republican, was speaker of the United States House of Representatives from 1995 to 1999, and is the author of the new novel "Duplicity." Bill Brazell, a partner at WIT Strategy, served on the board of the PKD Foundation from 2007 to 2013.

Kidney Watch 2016

Happy New Year from *Kidney News*. We are delighted to provide you comprehensive coverage of what is new and influential in the world of kidney disease. Please look for major innovations in how we present information and news stories in upcoming editions. We welcome your input into how we can best serve your need for information and communication, and can always be reached at kidneynews@asn-online.org.

For this issue, the *Kidney News* Editorial Board has tried to focus on several issues for the kidney community to follow in the coming year. We are hopeful that this issue will in part capture the excitement we feel about kidney care and all of the opportunities to improve our field and enhance patient care. Based on diverse interests, we have covered topics including new treatments, new policies and payment options, ongoing issues in recruiting trainees to nephrology, emerging technologies, as well as challenges in bringing new therapies to our patients. We hope this will spark your curiosity and attention and we look forward to providing updates on these issues and many more throughout the year.

Richard Lafayette, MD, FACP
Editor-in-Chief, Kidney News

A Step toward Measuring High-Value Care for Patients with Complex Chronic Disease

By Amy W. Williams

As health care moves forward in defining a system of accountable and valued care, aligning health care cost inflation with overall economic growth, and ensuring access to appropriate evidence-based services for all, physicians are being called upon to break down many barriers to achieving accountable valued care. These include right-sizing our outsized delivery system, correcting unwarranted variations in care, decreasing unnecessary health care spending, and improving patient-centered outcomes.

Part of this effort involves decreasing the escalating costs of Medicare and the variations in approaches and costs of care at the end of life. To help us reach these goals, the Centers for Medicare & Medicaid Services (CMS) continues to redefine the Physician Fee Schedule (PFS), strengthening the link to quality outcomes. Following this strategic path, CMS is increasingly focusing on patient-important outcomes (i.e., 30-day readmissions, mortality, patient safety indicators, hospital-acquired conditions) and efficiency of care in the inpatient setting, placing greater weight on clinical outcomes measures.

When we look at the hospital value-based purchasing (VBP) domains and trends in their weighting forecasts, we are beginning to see similar changes in the outpatient arena of patient care. In 2013, clinical processes accounted for 70 percent of hospital VBP scores, with patients' experience making up the remaining 30 percent. Patient outcomes measures were introduced to the VBP measurements in 2014, accounting for 25 percent of the overall score and decreasing the clinical process domain to 45 percent. In 2015, CMS included measures of efficiency (20 percent domain weight) while increasing the weight of care outcomes to 30 percent, maintaining patient experience at 30 percent and decreasing clinical process measures to only 20 percent. In 2016, the clinical process domain weight will be further decreased to only 10 percent of VBP scores, with patient outcomes increasing to 40 percent and efficiency and patient experience each accounting for 25 percent of the overall score. This reflects the trend toward measuring the value of care delivered (value = quality–safety–service/cost). This trend is also evident in the ESRD Quality Incentive Program measures for 2016, decreasing the number of report-only measures to three and increasing the clinical outcomes measures from six to eight.

The PFS final rule summary for 2016 is quite interesting in that it also reflects the emphasis on patient-centric outcome metrics and the shift away from reporting/process metrics. Moreover, it includes changes that will affect patient-important aspects of managing complex chronic disease such as CKD and that will help physicians and their care teams decrease the variations and cost seen now with end-of-life care, better meet patients' health care goals, and respect patients' preferences.

In 2016, the PFS includes a reimbursement for advanced care planning without exclusion of providers paid under the ESRD monthly capitation payment. By adding these steps in the care of our patients to a reimbursement plan, CMS recognizes the significance of shared decision-making and patient-focused end-of-life care—a step to achieving high-value care. To complement this, the Physician Quality Reporting System metrics will include referral to hospice for adults with kidney disease. Furthermore, to decrease the burden of documentation and reporting measures that do not lead to improved quality, as recommended by the American Society of Nephrology, CMS removed two measures under adult kidney disease: 1) hemodialysis adequacy solute measure and 2) the hemodialysis vascular access decision-making by surgeons measure.

Another step in eliminating barriers to delivering high-value care is the addition of a home dialysis Current Procedural Terminology code to bill for virtual (telemedicine) care visits. This will be particularly helpful in meeting the qualifications for home dialysis programs and in facilitating timely input from expertise in nephrology to care and education for patients in distant rural areas, or regions without ready access to nephrologists or nephrology care teams. These changes to the PFS, which support the importance of long-term care management for complex chronic diseases such as advanced kidney disease, are important steps in facilitating the delivery of patient-centered, valued specialty care, possibly leading to a decrease in variations in care by allowing knowledge sharing and continuity of care across distances.

As delivery of health care moves toward alternative payment models, nephrology as a profession and nephrologists as knowledge experts are highly experienced in creating care teams to achieve quality, safety, and service goals. After all, we were involved in the first CMS-directed pilot of VBP/pay for performance and bundled care payment with the ESRD Quality Incentive Program and Prospective Payment System, and now a select few are stepping into the ESRD seamless care organization pilot.

As the US population ages and the survival of those with complex chronic diseases and multiple comorbidities increases, our experience and expertise will allow us to lead the way in defining successful management of this "top of the pyramid," medically complex population. Our challenge, as care models evolve to reward quality and patient-centered care, will be to thoughtfully evaluate best practices throughout the disease trajectory of CKD in a scholarly manner and to inform the medical community, payers, and patients about how to better define and recognize truly value-based care for medically complex chronic disease.

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Fellowship Recruitment and the Future of the Nephrology Workforce

By Joseph Mattana

The past several years have seen a decline in the number of applicants for nephrology fellowship positions with about half of all programs having unfilled slots. It is anticipated that a further decline will be found for the current recruiting season. The recent *US Nephrology Workforce 2015: Developments and Trends* (1) from George Washington University (ASN Nephrology Workforce report) highlights many of the key issues that are likely to affect the future of the nephrology workforce, issues that are intrinsically linked to interest in nephrology and fellowship recruitment.

It is somewhat ironic that decreasing interest in nephrology careers is taking place at a time when great progress is being made in the care of patients with renal disease. For example, end stage renal disease (ESRD) incidence rates have been falling for the past several years, undoubtedly reflecting the efforts of nephrologists to use angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and other interventions to slow progression of chronic kidney disease (CKD).

Mortality rates for CKD have been falling and are declining at a rate faster than the non-CKD population. ESRD mortality rates are declining as well. There are new therapeutic regimens and remarkable pathophysiological and genetic insights in glomerular disease, transplantation, hypertension, electrolyte metabolism, and many other areas. Ongoing laboratory and clinical investigations continue to yield valuable results that are having a positive impact and continue to add to the excitement of being a nephrologist.

There are, however, a number of factors that are contributing to declining interest. There is a perceived lack of job opportunities and concern that this will be a continued problem. There is also a perception that the quality of life and compensation of the nephrologist is less compared to those in other specialties. Alternative careers have become more appealing, especially hospitalist medicine, regarded by many as being better compensated and having a better quality of life. The ASN Nephrology Workforce report indicated that about a third of nephrology fellows would not recommend nephrology to others. If practicing nephrologists are negative about their chosen specialty this can understandably be devastating for students and residents who are considering careers in the field.

The composition of the nephrology applicant pool will continue to have important implications for the future workforce as well. Applications from US medical graduates (USMGs) are decreasing. In the past, this has been counterbalanced by nephrology having a substantial pool of international medical graduates (IMGs), but as outlined in the ASN Nephrology Workforce report, IMGs face particular challenges in pursuing nephrology careers. While IMGs have less educational debt to manage compared to their USMG peers, they report having a harder time finding jobs, with 72.5% reporting having a difficult time finding a job with which they were satisfied in 2015. Only 62.7% of IMG fellows said they would recommend nephrology as a career. The percentage for USMGs recommending nephrology was somewhat higher at 74.4%.

While interest in nephrology has been declining in recent years, over the past 15 years there has been a large increase in the number of fellowship slots, with an almost 50% increase since 2000. The impetus for this increase has been based on past predictions of eventual shortages of practicing nephrologists. Projections of large increases in the numbers of ESRD patients have helped provide support for increasing fellowship slots. However, the demand for nephrologists has been complicated by a number of factors. First, while there continues to be an increase in the number of patients with ESRD, incidence rates for ESRD have decreased as noted above. Second, the models of care for patients with ESRD are in transition with nurse practitioners (NPs) and physician assistants (PAs) playing increasing roles. Third, as for ESRD, CKD care can involve not only NPs and PAs but internists as well, further affecting the demand for nephrologists. Finally, there is a maldistribution of the ratio of nephrologists to patients throughout the country, a problem without a simple solution as choice of where to practice is influenced by additional factors aside from patient location.

Fortunately, ASN is making great efforts together with the nephrology community to promote interest and provide a robust nephrology workforce for years to come, with many promising interventions being implemented and published. The variables discussed here and detailed in the ASN Nephrology Workforce report merit close observation.

Joseph Mattana is chief of the Division of Nephrology and Hypertension at Winthrop-University Hospital in Mineola, NY, and is a member of the Kidney News *Editorial Board.*

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Changing Payment and Care Models for Kidney Patients

By Richard Lafayette

After the signing into law of the Affordable Care Act in 2010, the Centers for Medicare & Medicaid Services developed the idea of accountable care organizations (ACOs) as a way to improve health care outcomes while controlling costs. ACOs are legal entities composed of physicians, other providers, clinics, and hospitals, with shared governance toward providing patient care. The idea is to share risk in the management of a given population toward providing high-quality, cost-effective care. It was expected that this approach would foster multidisciplinary preventive care that would improve health and avoid expenses. If organizations save money for Medicare while achieving quality metrics to assure full engagement of patients, they share in the savings. Ultimately, if they spend more, or do not provide quality care, their payments from typical fee-for-service charges are reduced. Thus, they must get a handle on the entire treatment of a patient from primary care to specialist care, including outpatient and inpatient treatment, to have some impact on the quality of care and associated costs.

For patients with chronic kidney disease (CKD), especially those with ESRD, this model brings up many challenges but also opportunities. CKD care is incredibly expensive, complex, and highly specialized. Patients have multiple comorbidities, are frequently hospitalized, and have wide variability in their care. Those already receiving dialysis are cared for under the present rules (at least the vast majority of patients covered by Medicare), with separate quality initiatives and monthly capitation for most of their dialysis-specific costs. Physicians are paid on the number of face-to-face visits per month. The general format of ACOs is that patients are enrolled by primary care groups, which determine the quality interventions and management. Specialists are not central to patient care.

For patients with CKD, it has been suggested that nephrologists have the experience, interaction, and skills to best coordinate the care of these patients, especially those with progressive or advanced disease. These ideas led to Medicare sponsoring the creation of ESRD seamless care organizations. These organizations are intended to capture the overall burden of care and costs for ESRD patients, with shared savings and risks and measures of quality and outcome. This experiment has rolled out slowly, largely embraced by large dialysis organizations and some large health care systems, but the results have not yet been well reported. The results should prove very interesting and should provide a key to whether or not other specialty-specific care models will go forward. Once evaluated, this may determine whether nephrologists and kidney care teams will become the central players in the care of patients with CKD, or rather a captured employed resource for other management organizations.

It strongly behooves us to become intensely involved in these experiments and other launches of ACOs and, in fact, all discussions of models of care of our patients. We must defend the health of kidney patients to the best of our ability while ensuring that the nephrology care team maintains its value and professionalism. The American Society of Nephrology has been closely involved with Medicare and other payers, and I hope all involved parties stay tuned and active in 2016 and beyond.

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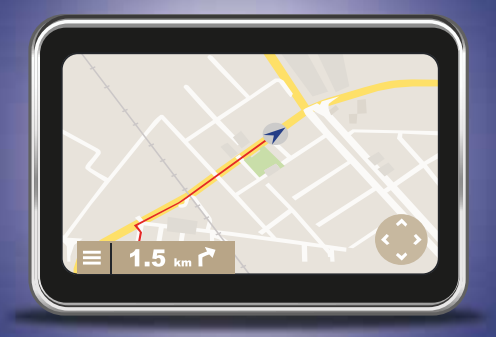

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The New Kidney Allocation System

By Udey S. Nori

Ever since deceased donor kidney transplantation became practical and accessible to all, several competing factors have shaped the kidney allocation system (KAS) in the US. On one hand, scientific progress has allowed vastly improved preservation techniques, and cross-matching has made it possible to increase the allograft half-life significantly. On the other hand, there continues to be a moral obligation to achieve equitability and fairness in organ allocation practices.

Over the past several years, other issues have become increasingly important: the demand for deceased donor kidneys continues to increase as the supply remains at a plateau, the organ discard rate remains unacceptably high, and more already-treated patients are returning to the list for repeat transplantation. Furthermore, very highly sensitized patients (with preformed anti-HLA antibodies) are harder to match and tend to have very much longer waiting times. Over the past two decades, several minor changes were made to the KAS (e.g., removing HLA-B antigen matching in the match run) to address these issues, but the most significant new KAS was implemented by the Organ Procurement and Transplantation Network/United Network of Organ sharing (OPTN/UNOS) in December 2014.

The overarching goals for the new KAS are as follows:

- Increase the life-years gained from each organ by matching donors and recipients on the basis of their health risk profiles. This is made possible by assigning an estimated posttransplant survival (EPTS) score to a recipient and matching it to the kidney donor profile index (KDPI) of the donor (Tables 1 and 2). This allows allocation of the best quality kidneys to the recipients with the highest predicted longevity.
- Increase the chance for transplantation for highly sensitized patients (high calculated panel reactive antibodies [CPRA]). This is made possible by expanding the geographic area for organ sharing, allowing these patients to have access to more potential donors.
- Improve procurement of organs from extended criteria donors that could potentially be used for patients with high (suboptimal) EPTS.
- Decrease the organ discard rate of kidneys that were not used despite being procured for transplantation.
- Standardize the waiting times: Patients with delays in evaluation for transplantation are to have their waiting time default to the dialysis initiation date.
- Allow transplantation of blood type A2/A2B donor kidneys into B blood type recipients, who are considered to be at low risk for acute rejection.
- Reduce the risk of listing for a second transplantation.

The OPTN/UNOS kidney transplantation committee released the early results of KAS in June 2015 and will continue to report detailed analysis 1 year and 2 years from implementation. Most of the observed transplantation trends were in keeping with the expectations of the KAS, but there were a few exceptions. The total number of transplantations and the number of patients added to the wait list remained stable over the 6 months after implementation of KAS.

Following are the four areas of significant gains from KAS:

- A sixfold increase in transplantations for patients with the highest CPRA of 99 percent to 100 percent, from 2.5 percent to 13.5 percent.
- An increase in nonlocal transplantations from 21 percent to 33 percent, indicating that more kidneys are being shared outside of the local area.
- Thirty-eight percent of African Americans received transplants compared with 32 percent before the new KAS, whereas the percentage of these patients on the wait list remains the same. The increase in African Americans receiving transplants under KAS was statistically significant. Credit given for dialysis duration before wait list registration was likely the main contributing factor to this increase.
- The proportion of longevity-mismatched transplants, defined as age difference between the donor and the recipient of more than 15 years, has decreased from 50 percent to 48 percent, as did the the proportion of high KDPI transplants to low EPTS candidates (3 percent to 1 percent).

A few unexpected trends to watch were also noted:

- A significant drop in the zero-mismatch transplantations from 8 percent to 4.5 percent, probably because of the increased priority given to high CPRA patients
- A higher organ discard rate of 20.3 percent compared with the pre-KAS era rate of 18.5 percent.

Overall, it is difficult to predict which of these early observations will be sustained over time. Because of the significant emphasis placed on equitability in allocation and increased organ use, most transplant recipients now have either more HLA mismatches or pre-existing anti-HLA antibodies. Whether this will lead to increased acute rejection or chronic alloantibody-mediated allograft injury remains to be seen. In other words, the gains made in terms of the equity and increased life-years of the allograft need to be significant in comparison with the downside of more transplantations with higher immunologic risk and higher dialysis vintage for the new KAS to be justified.

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Table 1
The Estimated Posttransplant Survival (EPTS) score

The EPTS is calculated from the following recipient characteristics:

- Age of recipient
- Number of years receiving dialysis
- Diabetes mellitus
- Prior kidney transplantation

Table 2
The Kidney Donor Profile Index (KDPI)

The KDPI is calculated from the following donor characteristics:

- Age
- Height
- Weight
- Ethnicity
- History of hypertension
- History of diabetes
- Cause of death
- Serum creatinine
- Hepatitis C virus status
- Donation after circulatory death status

SGLT-2 Inhibitors: What the Nephrologist Needs to Know

By Andrew J. King, MD

Be on the lookout for increased use of SGLT-2 inhibitors in 2016 after a recent study published in the *New England Journal of Medicine* demonstrated a lower composite rate of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke in high risk type 2 diabetics (n = 7020) treated with empagliflozin compared to placebo.

Reduction in death in the treated group was mostly due to a reduction in cardiovascular deaths (18% risk reduction). Active treatment also reduced renal events by 21% primarily related to a reduction in the development of microalbuminuria.

Empagliflozin is one of several SGLT-2 inhibitors now on the market. This class of drugs represents selective inhibitors of sodium glucose cotransporter 2 in the proximal tubule that lead to substantial glycosuria and hence, a reduction in blood glucose. Patients treated with these agents can have small decreases in weight (typically 2–4 kg) and systolic blood pressure (BP) (4–6 mm Hg), likely related to the osmotic diuresis that accompanies the glycosuria. The major side effect appears to be an increase in urinary tract and genital infections, some leading to septicemia and hospitalization. Ketoacidosis is another unusual complication typically seen within the first year and associated with another risk factor, e.g., fasting, alcohol, or reduction/discontinuation of insulin.

The hypoglycemic effects of SGLT-2 inhibitors diminish with worsening kidney function. SGLT-2 inhibitors are currently not indicated in patients with GFR <30 mL/min. A study using canagliflozin demonstrated hypoglycemic efficacy in CKD stage 3 with small reductions in GFR seen within 3 weeks of initiation of drug and a reduction in urinary albumin excretion (20–30% vs. 7.5% in controls). Others have found similar effects on GFR, BP, microalbuminuria, and progression of albuminuria. A small study of patients with type 1 diabetes demonstrated a reduction in glomerular hyperfiltration by empagliflozin under both euglycemic and hyperglycemic clamped conditions. The authors postulated that the SGLT-2 inhibitor restores tubular-glomerular feedback, leading to an increase in afferent arteriolar tone.

Taken together, these findings raise the intriguing possibility that early use of SGLT-2 inhibitors might have significant renal protective effects. Does one believe a reduction in proteinuria signals renal protection? Only time and well conducted clinical trials will answer this question as it relates to SGLT-2 inhibitors. However, kidney care givers should prepare to answer questions about the safety and efficacy of SGLT-2 inhibitors, their effects on the kidney, and how they perform in patients with various degrees of renal dysfunction.

Andrew J. King, MD, is affiliated with Scripps Clinic in San Diego, CA. Dr. King is a member of the Kidney News *Editorial Board.*

Smart Technologies Help Patients Manage Their Care

By Pascale H. Lane

Imagine putting your meal on a special plate. Its built-in scales and cameras identify your food and its quantity, and then send nutritional information to your smartphone. It may sound like science fiction, but such a product will be shipping soon! Now add a twist for patients. If you have diabetes, an app could tell you how much insulin to take. If you want to lose a few pounds, your phone may alert you to calorie intake. If you have chronic kidney disease, you could get information about potassium and sodium intake, and a reminder to take a certain amount of phosphate binder.

Health trackers so far have focused mostly on fitness, activity, and weight. Adding in networked instruments like blood pressure cuffs and nutritional supports can allow smartphones to become a hub for health management, especially for those with chronic disease. Digital information can then be shared with health care providers to improve patient education and adherence. Look for lots of progress in this arena in the next few years.

Pascale H. Lane, MD, is professor of pediatrics in the section of Pediatric Nephrology at the Oklahoma University Health Sciences Center. Dr. Lane was the founding editor of ASN Kidney News *and Editor-in-Chief for six years, and currently serves on the* KN *Editorial Board.*

New Options for Treating Hyperkalemia in 2016

By Edgar V. Lerma

Patients and physicians have new choices for treating hyperkalemia in 2016. The FDA recently approved patiromer calcium sorbitex (Relypsa, Redwood City, CA) and will likely reach a decision on sodium zirconium cyclosilicate (ZS-9) (ZS Pharma, San Mateo, CA) this year.

Recent approval of the new heart failure medication EntrestoTM (LCZ696; sacubitril/valsartan) has reinvigorated an interest by the health care community to optimize treatment regimens that include life-saving therapies such as angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs). These agents belong to a larger category of drugs known as renin-aldosterone-angiotensin-system (RAAS) inhibitors, and are known in some patients to increase serum potassium to dangerously high levels that can lead to life-threatening arrhythmias. Patients who have chronic kidney disease (CKD), advanced age, heart failure, and/or diabetes mellitus are particularly prone to developing hyperkalemia. Within the nephrology community, hyperkalemia has been reported in over half of all CKD patients (1). The onset of hyperkalemia, or fear thereof, may lead to discontinuation or suboptimal dosing of RAAS inhibitors in patients who could really benefit.

Current therapies for the acute and chronic management of hyperkalemia include sodium polystyrene sulfonate (SPS; Kayexalate), a nonspecific cation exchange organic polymer resin that may (or may not) provide temporary alleviation, but is fraught with serious gastrointestinal toxicities and undesirable binding to Mg^{2+} and Ca^{2+} and exchange with sodium. Other therapies, such as intravenous insulin and dextrose, sodium bicarbonate, or diuretics, provide only temporary relief in the emergent clinical setting, and strict regulation of dietary intake of potassium is difficult to enforce. Although dialysis can be effective, it is an invasive and expensive option, and potentially may be avoided now that new, orally administered, potassium reducing agents are on the horizon.

ZS-9 is an inorganic, non-absorbed, selective potassium ion trap that has 9 times the potassium-binding capacity of SPS and 125-fold selectivity for potassium over calcium and magnesium, compared with SPS. ZS-9 rapidly normalized serum potassium levels in patients with hyperkalemia in two double-blind, placebo-controlled, Phase 3 studies. ZS Pharma recently announced acceptance by FDA of a New Drug Application for ZS-9 for the treatment of hyperkalemia. The anticipated Prescription Drug User Fee Act (PDUFA) decision date is May 26, 2016.

ZS-9 has demonstrated acute and sustained potassium-lowering properties, with low rates of adverse events and no significant impact on other electrolytes in >1000 patients with hyperkalemia. ZS-9 activity was consistent across all patients, regardless of presence or absence of comorbidities, including CKD stage 4 or 5 and the use of RAAS inhibitors. In urgent treatment of severe hyperkalemia (serum potassium greater than 6 mEq/L), pooled analysis of the two phase 3 studies showed that treatment with a single 10 gram dose of ZS-9 lowered potassium as early as 1 hour after administration. Studies have shown that ZS-9 achieves and maintains normokalemia for up to 28 days with a safety profile comparable to placebo. Additional studies are ongoing to demonstrate the long-term efficacy and safety of ZS-9. Concerns regarding exchange of sodium to cause edema seem minor, but will be monitored.

The organic polymer resin patiromer calcium sorbitex (patiromer) has also shown potential to treat hyperkalemia where immediate responses are not required. Studies on patiromer were predominantly observational, with only a placebo-controlled trial of short-term maintenance of normokalemia in CKD patients maintained on RAAS. There is also a somewhat limited demographic profile, as these studies have mostly been conducted on white patients from Eastern Europe. In addition, patiromer releases calcium and binds to not only potassium but magnesium as well, resulting in hypomagnesemia in some patients. Nonetheless, it appears to be largely well tolerated and effective in the treatment of hyperkalemia in individuals with advanced CKD, those with congestive heart failure, and in diabetics.

If approved, ZS-9 will represent another promising new therapy for both the acute and chronic management of hyperkalemia. This innovative therapy warrants close attention for an FDA decision in 2016, and availability in the clinic shortly thereafter. We will then learn exactly where these new agents fit in for the care of patients.

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Disclosure: Edgar V. Lerma, MD, FACP, FASN, is a member of the ZS Pharma Steering Committee.

What We Learned From the Frequent Hemodialysis Network Trials

By John T. Daugirdas, on behalf of the Frequent Hemodialysis Network Trial Group

Why the FHN trials were done

To understand why the Frequent Hemodialysis Network (FHN) Daily and Nocturnal Trials were initiated, one simply needs to look at the relationship between single-pool Kt/V (spKt/V), dialysis frequency and standard Kt/V (stdKt/V), an equivalent kidney clearance, shown in Figure 1. As shown, the rather large separation (35 percent) between the values of spKt/V achieved in the randomized Hemodialysis Study (HEMO) groups was diminished to less than half of that amount when the doses were considered in terms of stdKt/V (1, 2). A stdKtV in a person with a total body water volume of 35 L is roughly equivalent to a continuous clearance of 7 mL/min. Multiplying by 1.18, the difference in stdKt/V of the two-dose arm, we get, for a patient of normative size, a comparison of an equivalent clearance of 7.0 versus 8.3 (7.0 × 1.18) mL/min. In this regard, it was not surprising that the HEMO dose comparison was completely negative. As shown, by moving to a schedule of six treatments per week, one would be able to achieve stdKt/V differences that would be potentially more meaningful, approaching 14 mL/min in the Daily Trial and 20 mL/min in the Nocturnal Trial (3). A second purpose of the FHN trials was to examine the effects of potentially better control of extracellular volume that might be expected with a more frequent dialysis schedule.

What was surprising

Recruitment

We knew that we would not be able to randomize the 2000 or so patients required to examine "hard" outcomes of mortality and hospitalization. We therefore chose two intermediate outcome composites: 1) mortality, and in survivors, change in left ventricular (LV) mass; and 2) mortality, and in survivors, change in physical health composite scores. Our initial goal was to randomize 250 patients for each trial. What we did not anticipate was how difficult the recruitment would be for the Nocturnal Trial (4–6). We randomized 245 patients in the Daily Trial. For the Nocturnal Trial, the randomization target had to be reduced twice because of recruitment challenges. The recruitment target was reduced to 150 and then ultimately to 90. Ultimately in the Nocturnal Trial, 87 patients were randomized (4, 5).

Residual kidney function

Our two studies really examined different populations of dialysis patients: the daily in-center patients were largely prevalent patients who had long dialysis vintage and minimal residual renal function, whereas home nocturnal dialysis patients were largely incident patients new to dialysis with substantial urine volumes and residual renal function. To maintain generalizability and to facilitate recruitment, a higher amount of residual kidney function had to be allowed in the Nocturnal Trial compared with the Daily trial. It is possible that the inclusion of patients with substantial urine output combined with the small sample size in the Nocturnal Trial combined to limit the ability of that trial to detect a possible beneficial outcome.

LV mass: volume control and residual kidney function

In the Daily Trial, the co-primary outcomes, death or change in LV mass and death or change in self-reported physical health (based on the Physical Health Composite of the RAND-36 health survey), were improved in the group assigned to "daily" (six per week) dialysis (4). In the Nocturnal Trial, there was little signal for self-reported physical health, and a similar signal for effect of more frequent dialysis on LV mass, which was not statistically significant because of the smaller sample size (5). It can be argued that both of these outcomes were related to extracellular fluid volume. Similarly, change in blood pressure was easily demonstrated in both trials (5–7).

We knew that echocardiographic assessment of LV hypertrophy (LVH), one of the co-primary outcomes, was unreliable in the situation of rapid shift in extracellular fluid, so we used magnetic resonance imaging. Still, given past experience, we anticipated that the majority of patients in both trials would have LVH. To our surprise, the incidence of LVH at baseline was only 34 percent in the Daily Trial and 28 percent in the Nocturnal Trial (8). Thus, for many of our patients, in terms of the primary outcome, we were looking for a fix for something that was not broken to begin with. In analyzing our results, we found that even relatively small amounts of residual urea clearance or urine volume may have had a treatment-modifying effect; in patients with substantial residual kidney function, there was very little trend toward a beneficial effect of more frequent dialysis on LV mass. Another interesting finding was that in the conventional dialysis group, there appeared to be no progression of LVH overall during a 1- to 2-year follow-up period. If our conventional dialysis treatment was so poor, one might expect progression of LVH with inadequate treatment. This was not seen, perhaps because of relatively good volume control in the patients randomized to three treatments per week, perhaps because of intensified attention to this aspect of care in a trial setting.

Anemia and nutrition

We hypothesized that more frequent dialysis and increased removal of uremic toxins would improve anemia and nutrition. There was no evidence of benefits of the frequent dialysis interventions in either of these domains (9, 10).

Some adverse effects, one unexpected

We found an increase in vascular access procedures among patients randomized to frequent hemodialysis, although there was no difference in vascular access survival (11). Vascular access was a pre-specified outcome, and potential effects of frequent dialysis in this domain were anticipated. However, we did not anticipate that more frequent dialysis might have an adverse effect on residual kidney function, which was evident in the Nocturnal Trial. We did not observe a more rapid decline in residual kidney function in the Daily Trial, presumably because only patients with residual urea clearance below 3 mL/min/35 L were eligible for enrollment, so it would have been more difficult to detect any change between treatment arms in terms of further decreases in residual function (12).

Prolongation of survival

As mentioned, neither of the two FHN trials had sufficient power to detect a change in survival. Still, at the outset of the trial, the investigators planned to examine the effects of frequent hemodialysis on death or non–access-related hospitalization occurring during each trial.

In the FHN Daily Trial, when the mortality analysis was extended beyond the initial 12-month trial period, a substantial, statistically significant benefit was seen among patients randomized to assignment to "daily" in-center hemodialysis. This difference in death rates was observed even though the majority of patients in the Daily Trial resumed a conventional schedule of three hemodialysis treatments per week after the 12-month study period (fewer than 1 patient in 6 continued with a schedule of four or more sessions per week in the 2 months after completion of the 12-month intervention), whereas the majority of excess deaths in the conventional arm occurred after year 1 (13).

In the Nocturnal Trial, a substantial number of patients either continued on, or began, an extended, frequent nocturnal dialysis schedule at the conclusion of the 12-month study period. Surprisingly, the group assigned to frequent nocturnal home treatments had a mortality rate that was substantially higher than the group assigned to initially receive three treatments per week at home (14). Given the small sample sizes and other issues, the significance of these mortality results was unclear, but Bayesian analysis helped put them into perspective. In both trials, the survival rates of enrolled patients were very high, even in those patients randomized to conventional three treatments per week. Such an effect might call into question the generalizability of the results from these two trials, especially so in the Nocturnal Trial, where excellent results in patients treated three times per week at home made it very difficult to detect any improvement. However, in the Daily Trial, the argument might turn in the opposite direction, i.e., that the inclusion of sicker patients (those with more baseline LVH and also more anuric patients) might have magnified the benefits of frequent "daily"

dialysis.

Thus, overall, the data suggest both advantages and some potential disadvantages of more frequent hemodialysis (Figure 2). The FHN Trial results give some potential guidance regarding selection of patients who might benefit from more frequent schedules (pre-existing LVH or severe hypertension, low levels of residual kidney function). The results also suggest that change to a more frequent schedule in the hope of improving anemia management or nutrition is not likely to be successful. Despite our cautionary findings regarding a possible increase of vascular access events with frequent dialysis, whether or not more frequent dialysis adversely impacts the vascular access is far from being settled.

To me, personally, it was a great honor and privilege to participate in both the HEMO and the FHN trials from the outset with a most outstanding and dedicated group of investigators and support staff. The valuable results from these two trials speak for themselves, and they also emphasize the utility of, and need for, more randomized trials in the field of dialysis care.

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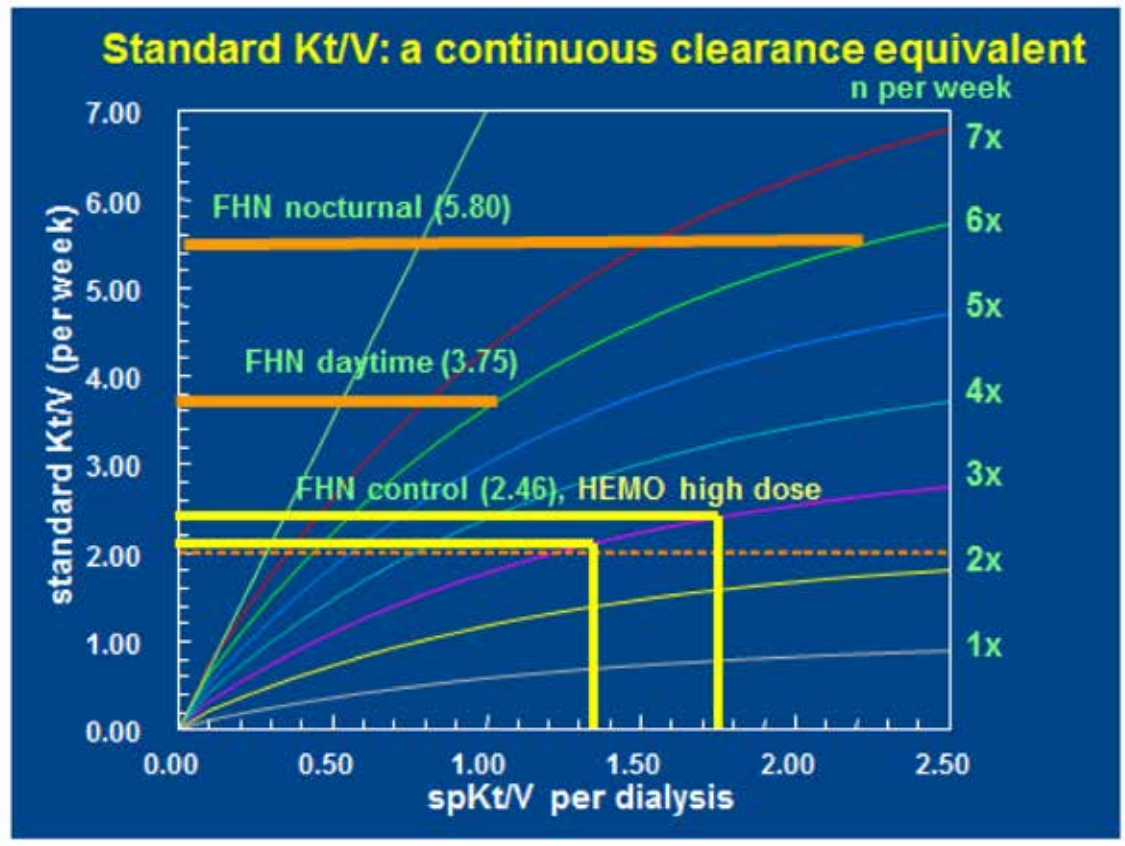

Figure 1

Standard Kt/V (approximate) in the HEMO and FHN trials. A standard Kt/V of 2.0 corresponds to an equivalent continuous clearance of approximately 7 mL/min in a patient with a total body water of 35 L. Abbreviations: FHN = Frequent Hemodialysis Network; HEMO = Hemodialysis Study.

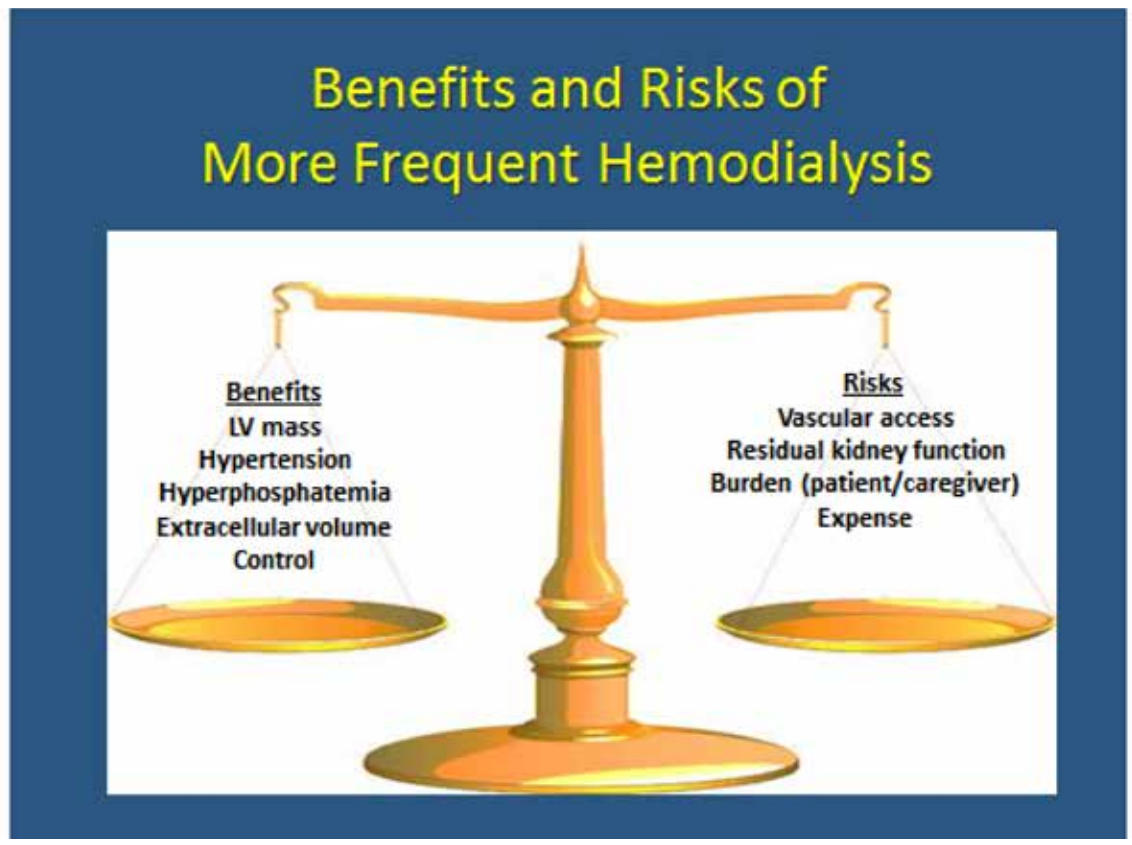

Figure 2

Benefits vs. potential risks of more frequent dialysis, as determined from the Frequent Hemodialysis Network trials.

Policy Update

Kidney Watch 2016

Several policy stories will affect the kidney care team in 2016

Continuing Shift toward Physician Payment for Quality of Care: MACRA

Implementation of a new law that entirely overhauls how Medicare pays physicians will be a major focus for ASN and the entire medical community in 2016. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) shifts physician reimbursement away from a fee-for-service system—paying for quantity of care—toward a value-based system that pays for quality of care. Physicians will have choices regarding how they participate in the new reimbursement system, opting either to participate in the "Merit-Based Incentive Payment System" (MIPS) or to participate in an "Alternative Payment Model" (APM).

Although many health professionals will be pleased to hear that MIPS sunsets three existing Medicare programs—the Physician Quality Reporting System, the Value-Based Modifier, and the EHR Meaningful Use program—MIPS will nonetheless assess quality, value, and EHR use in other ways yet to be determined. While MIPS and APMs won't be operational until 2019, ASN and others aim to work with Medicare to shape these programs to ensure they are as fair and feasible as possible for nephrologists in 2016 and beyond.

Innovating for Healthier Americans

A legislative capstone of 2015 was passage by the US House of Representatives of the 21st Century Cures Act, an ambitious bill aimed at accelerating the development and delivery of new therapies to patients. The Senate is working on introducing a corollary piece of legislation known as "Innovating for Healthier Americans." Although the Senate version is not likely to be an exact mirror of the House version, the overarching goals will remain similar.

Having successfully advocated for the inclusion of provisions including greater incorporation of patient preferences in US Food and Drug regulatory decision-making; supporting more high-risk, high-reward research at the National Institutes of Health (NIH); and increasing NIH funding in the 21st Century Cures Act, ASN will continue in 2016 to lay the groundwork for inclusion of these concepts in the Senate version. One potential hurdle to the package's passage into law in 2016 is how to pay for its likely significant cost. While the House used oil sales revenue to finance its bill, the Senate opposes that approach—and it remains to be seen what, if any, alternative payment approaches the Senate develops.

Chronic Conditions Legislation

Care for people with chronic conditions accounts for 93% of all Medicare spending, and the US healthcare system's fractured approach to care delivery does not effectively reward providers who provide the type of coordinated care these patients need. Sen. Johnny Isakson (R-GA) and Sen. Mark Warner (D-VA) convened a Chronic Conditions Working Group in 2015 to address this issue.

After soliciting input from ASN and other stakeholders, the working group is expected to release draft legislation for feedback, improvement, and introduction in 2016. Besides highlighting how kidney patients—among the most complex and vulnerable chronic disease patients—would benefit from the legislation, ASN's recommendations included improving care coordination, especially during care transitions, for patients with advanced CKD and other complex chronic conditions. The society also suggested permitting ESRD patients to enroll in Medicare Advantage (MA) plans and piloting of new care delivery programs specifically for kidney patients.

Treatment Options for Patients with Dialysis-Requiring Acute Kidney Injury (AKI)

In 2015, President Obama signed into law the Trade Preferences Extension Act. This law would allow dialysis-requiring Acute Kidney Injury (AKI) patients to receive treatment at a Medicare-certified End Stage Renal Disease (ESRD) facility. Currently, these patients face limited options for treatment, each of which comes with major challenges.

The new law has the potential to increase access to care for AKI patients who require dialysis, while simultaneously facilitating earlier hospital discharge. Implementation of the new law will be a major focus for ASN in the coming year.

Although many health professionals will be pleased to hear that patients with dialysis-requiring AKI now have outpatient treatment options, ASN contends that CMS must address areas of concern before final implementation. For example, the care and treatment of patients with AKI requiring dialysis is fundamentally different than that of standard care for patients with ESRD requiring dialysis. Recognition of the difference is critical in order for CMS to develop appropriate regulations, guidance documents, and survey tools, regarding clinical care guidelines or pathways, payment and reimbursement, and clinical quality value monitoring.

The Living Donor Act

A top legislative priority for ASN in 2016, the bipartisan Living Donor Act will help increase access to kidney transplants by:

- ***Protecting donors:*** The bill prohibits life, disability, and long term care insurers from denying or limiting coverage or from charging higher premiums to living organ donors.
- ***Securing jobs:*** The legislation clarifies that living organ donors can use FMLA time to recover from donation surgery and maintain their job security.
- ***Educating Americans:*** The bill directs the Department of Health and Human Services to update its educational materials regarding living organ donation to reflect the changes the legislation entails.

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Policy Ambassador Program

As part of ASN's goal of increasing congressional support for its policy priorities, the society will launch a new Ambassador Program this year. Starting with three or four ASN members appointed by the ASN Public Policy Board, the Ambassadors will work with their congressional districts and congressional representatives to raise awareness about kidney disease in their home districts and advance ASN's policy priorities in Congress.

Those efforts will include tours of dialysis centers and research facilities with the ambassadors' congressional representatives, newspaper op-eds, and letters of support for ASN priorities like federal funding for kidney research, legislative and regulatory remedies to address kidney health disparities, and other efforts to provide the highest quality care for patients with kidney disease.

The ambassadors and congressional representatives who participate in the program will receive personal and public recognition for their contributions. ASN looks forward to sharing information about the first ambassadors and participating congressional representatives in upcoming issues of *Kidney News*.

Kidney Research Advocacy Day

Since the ASN Research Advocacy Committee began Kidney Research Advocacy Day in 2012, the committee's annual visits to the National Institutes of Health (NIH) have helped to raise awareness about the burden of kidney disease and to build support for more investments in kidney research. When the committee returns to NIH in June, it will present specific recommendations of areas for kidney research that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) should prioritize.

In past years, the Research Advocacy Committee has also met with senior staff at the Department of Veterans Affairs (VA) Office of Research and Development, Patient-Centered Outcomes Research Institute, and Defense Advanced Research Projects Agency. Topics for discussion have included more support for both basic and innovative kidney research; the decreasing rate of kidney research grant applications, specifically MD-PhD grant application rates; bolstering the training pipeline for young investigators; and more inter-agency collaboration to advance kidney research.

ASN has also been working with a number of advocacy coalitions that successfully persuaded Congress to raise the budget caps for federal discretionary funding in 2016 and 2017. Thanks to bicameral, bipartisan support, the prospects look good for NIH and VA research program funding increases in those years.

Latest GWU Workforce Report Finds Nephrology a Specialty in Transition

By Kurtis Pivert

A new analysis of the US nephrology workforce confirms the specialty is in a transitional state, driven in part by changes in the health care delivery system. The latest George Washington University (GWU) Health Workforce Institute report examines other issues affecting the specialty, including the "All-In" nephrology Match and geographic distribution of practicing nephrologists.

The US Nephrology Workforce 2015: Developments and Trends (available online at http://www.asn-online.org/workforce) is the third in a series of studies published by ASN and produced in collaboration with GWU. In addition to analyzing new quantitative data on current and future nephrologists, the report examines qualitative assessments of the specialty drawn from focus groups of practicing physicians and leaders of major dialysis organizations.

Several interrelated workforce issues indicate nephrology continues to be in transition. Fragmentation in kidney care delivery and ceding common procedures to other specialties are among the contributing factors, according to Edward Salsberg, MPA, who led the GWU research team. The report notes that increased efficiencies and other health care delivery changes could reduce future demand for nephrologists.

"While indications are that need for nephrologists is rising, it is not clear how changes in delivery and financing will impact on the specialty," Salsberg told *Kidney News*. However, the move to population-based health plays to several of nephrology's strengths (including continuity of care and care coordination) and may offer new opportunities for the specialty.

Evaluating supply, distribution, and demand for new nephrologists is a key concern. Salsberg and colleagues observed geographic maldistribution between physician supply and the demand for specialized kidney care (using ESRD patients as a surrogate metric). Better alignment of nephrologists with demand for nephrology services is needed to ensure underserved areas maintain access.

Determining the number of new nephrologists needed to provide adequate care has been complicated by declining interest in the specialty among internal medicine residents. A continued drop in nephrology fellowship applicants in the National Resident Matching Program Specialties Matching Service led to creation of the ASN Match Task Force and adoption of an "All-In" policy, where all programs and positions must fill through the Match.

Preliminary data from the first "All-In" nephrology Match for Appointment Year (AY) 2016–2017 demonstrated an increase in certified fellowship slots and programs, affording a more complete view of the nephrology training landscape. A slight increase in the number of applicants preferring nephrology, US medical graduate applicants, and matched fellows over AY 2015 reversed recent trends yet may be due to this more accurate accounting. Likewise, increased Match participation may account for the substantial rise in unfilled positions (57%) and programs (37%) over AY 2015. Of note, the number of IMGs choosing nephrology continued to fall, extending a 6-year decline. GWU will closely assess the "All-In" Match in the next year.

Although GWU's in-depth analysis of the 2015 Nephrology Fellow Survey will soon be released, the report's initial assessment of survey data noted an increase in recent graduates having difficulty finding a job they were satisfied with. "While the job market for new nephrologists is limited, the number entering the specialty is decreasing, which may lead to more opportunities in the future," said Salsberg. "It will be important to continue to monitor these developments impacting on the specialty."

In addition to a complete analysis of the 2015 Survey of Nephrology Fellows, GWU will conduct a more detailed examination of nephrologist supply and demand using modeling tools developed at the UNC Sheps Center for Health Services Research. Salsberg underscored that distribution and access issues, as well as changes in the delivery and financing of kidney care, will remain a focus of their research in 2016.

Workforce research is part of ASN's commitment to ensure the highest quality care for the more than 20 million Americans with kidney diseases and millions more around the world. To learn more about ASN's broad, multifaceted approach to increase interest in the specialty and support nephrologists at all stages of their careers visit http://www.asn-online.org/about/bythenumbers/?ID=2

Findings

Excess Mortality from Type 2 Diabetes: Rates and Risk Factors

Interactions among age, glycemic control, and kidney disease have a major influence on the risk of death for patients with type 2 diabetes, according to a study in the *New England Journal of Medicine*.

The researchers matched 435,369 patients with type 2 diabetes, drawn from the Swedish National Diabetes Register, to 2.1 million population control individuals without diabetes. Excess mortality associated with type 2 diabetes was analyzed, including the role of glycemic control and renal complications.

At a mean follow-up time of nearly 5 years in both groups, mortality was 17.7 percent in patients with type 2 diabetes versus 14.5 percent in control individuals. Excess mortality from type 2 diabetes was "historically low": the adjusted hazard ratio (HR) for all-cause mortality was 1.15. Cardiovascular mortality was 7.9 percent versus 6.1 percent, respectively: HR 1.14.

For both all-cause and cardiovascular mortality, the risk increased with younger age, worse glycemic control, and more severe kidney complications. For diabetic patients under 55 with a glycated hemoglobin level of 6.9 percent or less, the HR for death of any cause was 1.92, compared with control individuals. By contrast, for patients 75 or older at the same level of glycemic control, all-cause mortality was somewhat lower than in control individuals: HR 0.95.

For patients younger than 55 with normoalbuminuria and a glycated hemoglobin level of 6.9 percent or less, the HR for death was 1.60, compared with control individuals. Again, older diabetic patients with normoalbuminuria and good glycemic control had lower all-cause mortality than did control individuals: HR 0.76 for patients 75 or older and 0.87 for those 65 to 74.

The data suggest wide variation in excess mortality among patients with type 2 diabetes, based on age, glycemic control, and renal complications. Patients under age 55 are at substantially higher risk even if they have good glycemic control and normoalbuminuria.

Discussing the implications for efforts to reduce excess mortality among patients with type 2 diabetes, the authors highlight the importance of reducing renal complications in all age groups. They write, "[E]xcess mortality among younger patients with chronic kidney disease was approximately 15 times as high as that in controls" [Tancredi M, et al. Excess mortality among persons with type 2 diabetes. *N Engl J Med* 2015; 373:1720–1732].

Sources Yield Differing Data on Comorbidity in Dialysis Patients

For patients starting dialysis, the comorbidity reported on the Medical Evidence Report (MER) often differs from that identified from Medicare claims, reports a study in the *American Journal of Kidney Diseases.*

The study included 45,357 Medicare-eligible patients starting maintenance dialysis during the second half of 2007, 2008, or 2009. The prevalence of 12 comorbid conditions was assessed from claims during the 6-month period before the index date, the MER, and claims during the 3-month period after the index date. Agreement between these three sources of data was assessed.

The prevalence of comorbidity based on claims during the 6 months before patients started dialysis generally exceeded that based on the MER. Agreement was low to moderate, with κ statistics ranging from 0.07 for drug dependence to 0.69 for diabetes. The conditions with the largest absolute variation were atherosclerotic heart disease, congestive heart failure, chronic obstructive pulmonary disease, other cardiac disease, and peripheral vascular disease. The degree of discordance varied significantly by age, race, sex, and ESRD.

The analysis of 23,930 patient-years of follow-up included 8930 deaths. In predicting risk of death, claims from the 3 months after dialysis initiation outperformed the designations from the MER, with C statistics of 0.674 versus 0.616, respectively. Based on the difference between the MER and claims data, the standardized mortality ratios differed by more than 10 percent at 26.5 percent of dialysis facilities and by more than 20 percent at 12.8 percent of facilities.

The MER is a major source of comorbidity data for risk adjustment of quality metrics for dialysis facilities. The new study shows substantial variations between comorbidity assessed by the MER compared to Medicare claims data before and after initiation of dialysis.

"These patterns may engender bias in risk-adjusted quality metrics," the researchers write. They suggest that claims made during in the first 3 months after patients start dialysis might be a better source of data on comorbidity [Krishnan M, et al.: Comorbidity ascertainment from the ESRD Medical Evidence Report and Medicare claims around dialysis initiation: a comparison using US Renal Data System. *Am J Kidney Dis* 2015; 66:802–812].

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